Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Second Quarter 2019 Financial Results

PRINCETON, N.J., Aug. 13, 2019 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, announced today its recent accomplishments and financial results for the quarter ended June 30, 2019.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "It is an exciting time for Soligenix. We are now approaching data read-out in two Phase 3 clinical programs. We have completed the approximate 90 subject enrollment necessary to support the interim efficacy analysis of our pivotal double-blind, placebo-controlled Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. This interim analysis, to be conducted by the independent Data Monitoring Committee (DMC) for the trial, is anticipated to occur in September 2019. We expect completion of full enrollment in the study in the second half of 2019, with final top-line results anticipated in the first half of 2020, pending the DMC recommendation."

Dr. Schaber continued, "Following the positive recommendation received from the independent DMC for our pivotal double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), we continue to enroll patients and anticipate completing study enrollment in the second half of 2019, with final top-line results in the first quarter of 2020."

Soligenix Recent Accomplishments:

- On July 29, 2019, the Company announced that the European Patent Office had issued two patents, both titled "Topically Active Steroids for use in Radiation and Chemotherapeutics Injury". The new patents (#2,373,160 and #2,902,031) claim use of oral beclomethasone 17,21-dipropionate for treatment of damage to the gastrointestinal tract as a result of acute radiation injury, including total body irradiation in an accidental or biodefense context. To view this press release, please click here.
- On July 8, 2019, the Company announced the appointment of Ms.Diane L. Parks, an accomplished businesswoman and commercial executive with an extensive record of driving profitable growth for large pharmaceutical and biotech companies, to its Board of Directors. To view this press release, please click here.
- On May 28, 2019, the Company announced that it would be participating in a biodefense contract for the development of medical countermeasures against bacterial threat agents, with Soligenix awarded a subcontract of approximately $600,000 over 3 years. To view this press release, please clickhere.
- On April 23, 2019, the Company issued an update letter from Dr. Schaber. This letter provided an update as well as further guidance on the development programs for 2019. To view this press release, please click here.
- On April 18, 2019, the Company announced it had reached a significant milestone in the Phase 3 clinical study (the "DOM-INNATE" study) for SGX942 (dusquetide) in the treatment of oral mucositis in patients with head and neck cancer. Patient enrollment was sufficient to support the interim efficacy analysis by the independent DMC. In accordance with the clinical protocol, approximately 90 subjects had been enrolled into the study as required for the planned interim efficacy analysis. To view this press release, please click here.

Financial Results – Second Quarter Ended June 30, 2019

Soligenix's revenues for the quarter ended June 30, 2019 were $1.5 million as compared to $1.7 million for the quarter ended June 30, 2018. Revenues included payments on a contract in support of RiVax®, in addition to the grants received to support the development of SGX301 for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer.

Soligenix's basic net loss was$2.1 million, or ($0.12) per share, for the quarter endedJune 30, 2019, as compared to $1.6 million, or ($0.18) per share, for the quarter endedJune 30, 2018.

Research and development expenses were $1.9 million as compared to $1.2 million for the quarters ended June 30, 2019 and 2018, respectively. The increase in research and development spending for the three months ended June 30, 2019 was primarily attributable to higher clinical trial expenditures relating to the two pivotal Phase 3 studies for SGX301 and SGX942, compared to the same period in 2018.

General and administrative expenses were $0.8 million as compared to $0.7 million for the quarters ended June 30, 2019 and 2018, respectively.

As of June 30, 2019, the Company's cash position was approximately$7.0 million.

About Soligenix, Inc.

Soligenix is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. Our Specialized BioTherapeutics business segment is developing SGX301 as

a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID), the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Threat Reduction Agency (DTRA).

For further information regarding Soligenix, Inc., please visit the Company's website atwww.soligenix.com.

This press release may contain forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the U.S. Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the Priority Review Voucher (PRV) program or the amount for which a PRV for RiVax® can be sold. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission, including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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